REMARKS

Reconsideration and withdrawal of the objections and rejections to the application are respectfully requested in view of the amendments and remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 38-86 are present in the application. Claims 68-86 have been added, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 41 and 55-64 have been withdrawn, and claims 38-40, 42-54 and 65-86 are currently under examination. Additionally, the specification has been amended, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, as originally presented and as herein presented, are patentably distinct, and that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The additional claims, as presented herein, are not added for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE OBJECTION TO THE PRIORITY CLAIM IS OVERCOME

The March 25, 2003 Office Action alleged that one or more conditions for receiving benefit of an earlier filing date under 35 U.S.C. §120 had not been satisfied. Specifically, the Office Action stated that the specification of the present application referred only to French Application No. 98 0877, and failed to mention U.S. Application Serial No. 09/347,594. The objection is respectfully traversed.

The present application was filed as a divisional of U.S. Application Serial No. 09/347,594; accordingly, the specification of the present application is identical to that of U.S. Application Serial No. 09/347,594, such that the priority information contained in the first paragraph is that of U.S. Application Serial No. 09/347,594.

At the time of filing the present application, a Preliminary Amendment was filed concurrently (on February 16, 2001), which amended the priority claim to include a reference to

U.S. Application Serial No. 09/347,594. As it appears that this portion of the Preliminary Amendment has not been considered, the amendments herewith have properly updated the priority information, such that it now includes a reference to U.S. Application Serial No. 09/347,594. Consequently, reconsideration and withdrawal of the objection to the priority claim is respectfully requested.

III. THE OBJECTION TO THE DRAWINGS IS OVERCOME

The Office Action objects to the drawings because Figure 5b was allegedly missing from the drawings filed February 16, 2001. The objection is respectfully traversed.

12 sheets of drawings, including Figure 5B were filed on February 16, 2001, concurrent with the filing of the application. Accordingly, the Utility Application Transmittal indicated that 12 sheets of drawings were filed therewith, and the Filing Receipt mailed April 24, 2001 indicated that 12 sheets of drawings had been received (*See* exhibits 1 and 2).

Additionally, this application was filed as a divisional of U.S. Application serial No. 09/347,594, now U.S. Patent No. 6,217,883, such that the disclosure of the present invention is identical to that which was filed in U.S.S.N. 09/347,594, a disclosure that included Figure 5b.

Accordingly, Applicants have included herein a copy of Figure 5b with an Amendment inserting Figure 5b into the drawings. This amendment does not constitute new matter for the reasons set forth above, namely that Figure 5b was, in fact, filed February 16, 2001 with the remainder of the drawings, and that Figure 5b was present in U.S.S.N. 09/347,594, of which this application is a divisional application.

Consequently, reconsideration and withdrawal of the objections to the drawings are respectfully requested.

IV. THE OBJECTION TO THE SPECIFICATION IS OVERCOME

The Office Action objected to the specification because of the presence of two distinct abstracts. The amendment herein cancels the second abstract, such that the objection is moot. Consequently, reconsideration and withdrawal of the objection is respectfully requested.

V. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 42 was rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make or use the present invention. The rejection is respectfully traversed.

Specifically, the Office Action states that the deposit statement at pages 2-3 of the specification is not sufficient because it does not indicate the extent of public availability.

The undersigned, as Applicant's attorney, hereby declares and states that:

Accession Nos. V97100219, V97100218 and V97100217 were deposited under the Budapenst Treaty at the ECACC (European Collection of Cell Cultures, Centre for Appliced Microbiology and Research, Porton Down, Slaisbury, Wiltshire SP4 0JG, United Kingdom on October 2, 1997;

Accession No. V98011608 was deposited with the ECACC on January 16, 1998;

For all of the above mentioned deposits:

(a) during the pendency of this application, acess to the inventio will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit was made; and,

(e) the deposit will be replaced if it should ever become inviable.

As the above statement is set forth over the signature of Applicant's attorney of record, it is respectfully submitted that the deposits made under the Budapest Treaty are now sufficiently described to be in compliance with MPEP §2404.01. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112 is respectfully requested.

The Office Action also rejected claims 38-40, 42-54 and 65-67 under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for protecting against porcine parvovirus infection and inducing an immune response in a porcine subject against porcine

circovirus, allegedly is not enabled for a vaccine to treat and prevent porcine circovirus infection. The rejection is respectfully traversed.

It is respectfully submitted that the assertions in the Office Action that undue experimentation is required to practice the instantly claimed invention are inaccurate. The Examiner is respectfully invited to review *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988), wherein the Federal Circuit stated at 1404 that:

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing the factors summarized in *In re Wands*. These factors include, for example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims; all of which must be taken into account.

Contrary to the Examiner's allegations to the contrary, the instant invention is enabled. For example, pages 8-10 of the specification clearly indicate how the compounds of the present invention are made. Further, pages 11-31 of the specification contain twenty-one examples for the production and testing of the instantly claimed vaccines. In addition, the methods needed to practice the invention were well-known to the skilled artisan.

Accordingly, the Examiner's attention is resepectfully directed to the following experiments performed by the inventors, each of which demonstrate the effectiveness of the present invention in treating or preventing PMWS or PCV infections:

* * * * *

Example A: Serology analysis after one administration of a PCV-2 vaccine adjuvanted with the TS6 emulsion

10 specific pathogen-free (SPF) piglets, 2-3 months old, are randomly allocated into 2 groups.

One group of 5 piglets is vaccinated (on day 0) with 2 ml of a vaccine containing inactivated PCV-2 imp1010 strain (Accession No. V9700218) at 6.8 log10 $CCID_{50}$ per dose (vaccinated group) by the intramuscular route with a syringe.

One control group of 5 piglets was not vaccinated (control group).

Blood samples were taken at D0, D7, D14, D21 and D28 post vaccination for the titration of the PCV-2 ORF2 antibodies by ELISA.

Groups	ELISA (log10)	D0	D7	D14	D21	D28
Vaccinated	Mean	1.00	2.53	3.50	3.45	3.88
	Standard deviation	0.00	0.89	0.79	0.84	0.37
Control	Mean	1.00	1.00	1.00	1.00	1.27
	Standard deviation	0.00	0.00	0.00	0.00	1.24

All the pigs vaccinated show a significant anti PCV-2 ORF2 antibodies response, 7 to 40 days after vaccination.

Example B: Protection after the administration of a PCV-2 vaccine adjuvanted with the TS6 emulsion

16 SPF piglets, 4-5 days old, were randomly allocated into 2 groups.

One group of 8 piglets was vaccinated twice (on day 0 and on day 21) with 2 ml of the vaccine containing inactivated PCV-2 imp1010 strain at 7.55 log10 $CCID_{50}$ per dose (vaccinated group) by the intramuscular route with a syringe.

One control group of 8 piglets was not vaccinated (group control).

All the piglets were challenged on day 35 with 10 ml containing about 5.5 log10 $CCID_{50}$ per ml of PCV-2 Imp1011-48285 strain (deposited at the ECACC, under the accession number V98011608), by intranasal route (5 ml for each nostril).

The PCV-2 ORF2 antibodies have been followed-up by ELISA and seroneutralisation (SN).

The clinical score has been calculated for the following clinical signs:

Score	0	1	2
Prostration	No	Moderate	High
Dyspnea	No	Moderate	High
Anemia (color of the piglet skin)	Pink	White	Yellow
Coughing	No	Yes	
Anorexia	No	Yes	
Vomiting	No	Yes	
Rectal temperature	t<40°C	39.9°C<t<41°C	t>40.9°C
Weight gain during the week n is superior of the weight gain during the week n-1	Yes	No but > 100g/day	No but < 101g/day
Death	No	Yes*	

* In case of death, the score used is the value corresponding to the day before death.

The lesion score has been calculated for the following signs:

Score	0	1	2	3
Corpulence	Normal	Lean	Very lean	Rachitic
Carcass aspect	Normal	White	Yellow	
Mucosa	Normal	White	Yellow	
Subcutaneous connective tissue	Normal	Bright	Yellow	
Superficial lymphatic ganglions	Normal	1 fat and/or white and/or congestive	> 1 fat and/or white and/or congestive	> 1 very fat and/or white and/or congestive
Thoracic discharge	No	Bright thoracic cavity	Visible presence	
Hearth	No lesion	Lesion		
Lung	No lesion	Lesion		
Pleura	No lesion	Small lesions	Large lesions	
Mediastinal lymphatic ganglions	Normal	1 fat and/or white and/or congestive	> 1 fat and/or white and/or congestive	> 1 very fat and/or white and/or congestive
Abdominal cavity	Normal	Bright	Visible ascites liquide	
Peritoneum	No lesion	Lesion		
Stomach	No lesion	Lesion	Ulcer	
Small intestine	No lesion	Lesion		
Intestine	No lesion	Lesion		
Mesenteritic lymphatic ganglions	Normal	1 fat and/or white and/or congestive	> 1 fat and/or white and/or congestive	> 1 very fat and/or white and/or congestive
Peyers plaques	Not visible	Visible only in one intestinal segment	Visible in several intestinal segments	Visible in several intestinal segments and very important
Liver	No lesion	Lesion		
Kidneys	No lesion	Lesion		
Bladder	No lesion	Lesion		

Groups	**vaccinated**	**control**
Serology ELISA at D30 (log10)	4.1 +/- 0.70	2.8 +/- 0.50
Serology ELISA at D63 (log10)	5.2 +/- 0.28	3.4 +/- 0.67
Serology SN at D30 (log10)	3.4 +/- 0.25	1.6 +/- 0.23
Serology SN at D63 (log10)	3.7 +/- 0.31	2.2 +/- 0.53
PCV-2 in feces (% of positives)	40	61

PCV-2 in mediastinal ganglions (% of positives)	25	100
Clinical score	14	31
Lesion score	9.8	18.8

The results observed are statistically different between vaccinated and unvaccinated pigs.

* * * * *

Accordingly, the above demonstrates that the present invention is functional in treating or preventing PMWS or PCV infection and does not require undue experimentation as alleged in the Office Action. Should the Examiner wish to have the above in the form of a Declaration, Applicants will gladly provide the same. Thus, applying *Wands*, the following, *inter alia*, is clear: the quantity of experimentation necessary to practice the invention is low; the amount of guidance in the specification is high; the nature of the invention is not such that "an inordinate amount of experimentation" is required; the relative skill of those in the art is high; and the breadth of the claims is narrow. Thus, and contrary to the allegations in the Office Action, undue experimentation would not be necessary to practice the instantly claimed invention.

Furthermore, new claims 68-86 are directed towards compositions for eliciting a protective immunological response against porcine parvovirus and an immunological response against porcine circovirus comprising at least one porcine parvovirus antigen and at least one porcine circovirus antigen, and a veterinarily acceptable vehicle or excipient. The recitations of the new claims were specifically stated in the Office Action as being enabled: the specification is "enabling for protecting against procine parvovirus infection and inducing an immune response in a porcine subject against porcine circovirus." Office Action at 6. Consequently, it is believed that new claims 68-86 are not subject to the 35 U.S.C. §112 rejections discussed above, and that these claims should be considered allowable.

Consequently, reconsideration and withdrawal of the 35 U.S.C. §112, first paragraph, rejections for alleged lack of enablement is respectfully requested.

VI. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 38-40, 42-54 and 65-67 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-11, 22 and 24-30 of U.S. Patent No. 6,217,883. The rejection is respectfully traversed.

Although Applicants believe a Terminal Disclaimer is not required, Applicants will provide a Terminal Disclaimer in order to place the application in condition for allowance after such time that allowable subject matter has been noted. Accordingly, it is respectfully requested that the double patenting rejection be held in abeyance until the claims are deemed allowable.

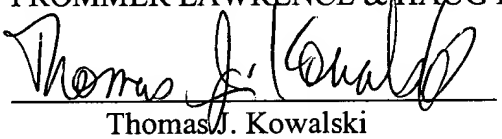
REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview, with supervisory review, is respectfully requested, prior to issuance of any paper other than a Notice of Allowance, and the Examiner is additionally respectfully requested to telephonically contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

By this paper, this application is in condition for allowance. Favorable reconsideration of the application, reconsideration and withdrawal of the rejections of and objections to the instant application, and prompt issuance of the Notice of Allowance, or an early interview, with a view towards reaching agreement on allowance, are, therefore, all earnestly solicited.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: 

Thomas J. Kowalski
Reg. No. 32,147
Angela M. Nigro-Collison
Reg. No. 51,107
Tel. (212) 588-0800